UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,552	08/02/2001	Hideakira Yokoyama	0020-4883P	4627

2292 7590 06/18/2003

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER
JAGOE, DONNA A

ART UNIT	PAPER NUMBER
1614	18

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/890,552	Applicant(s) YOKOYAMA ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-8 and 11-19 are pending in this application.

Response to Arguments

Applicant's arguments with respect to claims 1-8 and 11-17 have been considered but are moot in view of the new ground(s) of rejection.

Specification

A substitute specification including the claims is required pursuant to 37 CFR 1.125(a) because there are numerous grammatical errors in the specification such as page 2, lines 13-15 wherein it recites "In addition, it is known that essential oils alleviate headache in using as an aromatherapy, but they have a demerit being lack in simplicity on their use". The examiner is not sure of the meaning of the example sentence above. Is aromatherapy, too simplistic or too complicated? Another example can be seen on page 5 of the instant specification, lines 12-15 wherein it recites "On the other hand, when its amount is more than 60% by weight per total weight of base, it is difficult to mix with other substances and to use the polyhydric alcohol so much is not desirable".

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the

substitute specification relative to the specification at the time the substitute specification is filed.

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

Claim Objections

Applicant is advised that should claim 1 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 16 recites the limitation "the ointment claimed in claim 14" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim since there is not an ointment recited in claim 14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3, 4, 5, 14 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Karita U.S. Patent No. 6,190,685 B1.

The claims are drawn to an externally applicable pharmaceutical composition consisting essentially of l-menthol and one or more essential oils selected from the group consisting of lavender oil, juniper oil, peppermint oil, rose oil and rosemary oil in a pharmaceutically acceptable base such as a patch.

Karita teaches a patch formulation comprising essential oils such as l-menthol (column 6, line 49), peppermint oil (column 6, line 46), rosemary oil (column 6, line 66 to column 7, line 2), and Lavender oil (column 7, lines 19-25). The essential oils are added to a base material of water and a resin having a high molecular weight (column 9, lines 21-28) such as polyvinyl alcohol and cellulose (column 10, lines 4-20). The composition is formed into a percutaneous agent such as a sheet such as paper or a non-woven fabric (column 11, lines 7-42). Applicant has amended claims 1 and 18 to include the transitional phrase "consisting essentially of". As noted in the MPEP 2111.03 the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). The instant specification recites "In addition, it is known that essential oils alleviate headache in using as an aromatherapy". Further it recites "The present inventors have extensively studied in order to obviate the above mentioned demerits, and as a result, have unexpectedly found that migraine can be alleviated by dermally administering to human a drug containing l-menthol and an essential oil as active ingredients." Returning to the MPEP, it recites, "If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. Since the instant specification does not specify in the recitation above, unexpected results of one essential oil over another, or that one would work

particularly well over another, the transitional phrase "consisting essentially of" does not patentably distinguish the instant application from the prior art patch comprising essential oils and l-menthol. Regarding the intended use as a headache/migraine remedy, the intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Since the essential oil patch of the patent is capable of performing the intended use of relieving a migraine, then it meets the claim.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Tanoue et al. U.S. Patent No. 5,886,011 A.

The claim is drawn to external administration of an ointment comprising l-menthol and peppermint oil.

Tanoue et al. teach ointment for relief of migraine pain (column 6, line 45) comprising *inter alia* l-menthol and peppermint oil (column 8, line 52 to column 9, line 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-8, 14-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamiya et al. U.S. Patent No. 5,780,047 A.

The claims are drawn to patch and ointment formulations comprising l-menthol and one or more essential oils as active ingredients into a pharmaceutically acceptable base containing a hydrophilic high-molecular weight compound, a polyhydric alcohol and water and wherein the shape of the patch is a rectangle, ellipse, triangle, boomerang or face-mask shape.

Kamiya et al. teach patch formulations comprising essential oils such as peppermint oil, l-menthol from 0.01 to 10% (column 10, lines 18-20) and lavender oil (column 7, lines 28-38). The patch formulation contains a water-soluble polymer such as sodium carboxymethyl cellulose (column 3, lines 22-29), gelatin (column 4, lines 41-52) and polyvinyl alcohol such as ethylene glycol (column 5, lines 4-15). The patch adheres to the skin in specific areas such as shoulder, neck and lower back. It does not specifically recite the shapes of the patch as in the instant application. It would have been obvious to employ a rectangle, ellipse, triangle, boomerang or facemask shape for a patch to relieve a headache. One would have been motivated to employ a shape, such as a rectangle, for a patch formulation designed to relieve a headache because a rectangle shape would fit easily on the headache sufferer's forehead. Although ointment formulations are not recited, it would have been obvious to employ an ointment formulation since an ointment would be expected to work equally well for alleviating a migraine/headache.

Claims 11-13, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gobel et al. Phytomedicine Vol. 2(2), pages 93-102, 1995 (from IDS dated 11/2/01) in view of Davis et al. U.S. Patent No. 5,665,378 A.

The claims are drawn to a method of alleviating a migraine comprising administering an externally administered composition consisting essentially of the active ingredients l-menthol and one or more essential oils selected from the group consisting of lavender oil, juniper oil, peppermint oil, rose oil and rosemary oil and a

pharmaceutically acceptable base, wherein the composition is an ointment or a patch and it is applied to the region of the face, forehead, nape of neck or temple.

Goebel et al. teach that essential oils, especially of peppermint oil to alleviate headache is based on several assumptions. Local application of peppermint oil generates a long-lasting cooling effect on the skin, caused by a steric alteration of the calcium channels of the cold-receptors. Further, it was shown that peppermint oil inhibits, non-competitively, 5-hydroxytryptamin (serotonin) and substance P-induced smooth muscle contraction in animal models. It is also known that peppermint oil induces a significant increase of the skin blood flow of the forehead after local application measured by laser Doppler. A significant analgesic effect with a reduction in sensitivity to headache was produced by a combination of peppermint oil and ethanol. It does not teach l-menthol as an analgesic. Davis et al. teach menthol is a secondary alcohol obtained naturally from peppermint or other mint oils or prepared synthetically. Further Davis et al. teach that menthol has many uses as an ingredient in various medicinal preparations due to its analgesic, local anesthetic and counter irritant properties. It is known in the pharmaceutical art that menthol acts to enhance the percutaneous transfer of systemically active drugs in mammals (column 3, lines 8-14). It would have been made obvious to one of ordinary skill in art at the time it was made to employ l-menthol and an essential oil such as peppermint oil to relieve a migraine headache since peppermint oil is known to impart a cool feel, inhibit substance P and has a muscle relaxing effect and since menthol is known in the pharmaceutical art to promote percutaneous transfer (of the peppermint oil) and menthol has an analgesic and local anesthetic effect in itself.

Regarding the argument made by the applicants that the prior art addresses headache and not migraine headache, while the etiology of the pain is not the same, (vascular vs. muscular) both headache and migraine headache result in pain to the patient. Since the above compositions result in relief of pain and in the case of peppermint oil, a significant increase of the skin blood flow, it would be expected to relieve vascular headache (migraine) pain as well as headache pain.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

WILLIAM R. A. JARVIS
PRIMARY EXAMINER
ART UNIT 1614

Donna Jagoe
Patent Examiner
Art Unit 1614

dj
June 15, 2003